**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 7 1999

SP 99P-4167/CP 1

George Green
President
A & G Pharmaceuticals, Inc.
P. 0. Box 365
Clarksburg, NJ 085 10

Dear Mr. Green:

We refer to your suitability petition filed September 20, 1999, in which you requested permission to submit an abbreviated new animal drug application (ANADA) for a generic product with a dosage form that differs from that of an approved new animal drug. The proposed pioneer product is Phoenix Scientific's PHENYLBUTE™ (phenylbutazone tablets) which is intended for use in horses (NADA 91-8 18).

Your proposed product differs from the pioneer product in dosage form and therefore delivery method. The pioneer product is a tablet, whereas your proposed product is a powder administered in a small amount of feed. The dosage of active ingredient per pound of body weight will be the same.

Change in dosage form is one of the five variances in the pioneer product which can be considered through a suitability petition under section 5 12(n)(3) of the Federal Food, Drug, and Cosmetic Act, as amended. We are required to approve the petition unless we determine that investigations must be conducted to establish the safety and effectiveness of the proposed generic product.

Your suitability petition is approved. Approval of the suitability petition does not alter the requirements for approval of the ANADA, nor assure approval of the ANADA.

In addition to the study to show bioequivalence between the pioneer and generic products, we may require you to conduct a palatability study with the generic product. Palatability is not directly related to effectiveness. Palatability studies may be required in an ANADA with regard to the change in dosage form under section 5 12(n)(l)(D) of the FFDCA. We recommend that you submit protocols for our evaluation before initiating any studies.

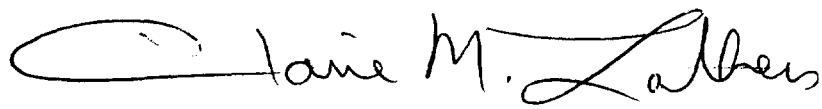
We will conduct a definitive labeling review when the ANADA for the proposed generic product is submitted to the Center. The generic labeling should be a verbatim copy of the approved labeling for the pioneer, with certain allowable differences, such as directions for administration of the powder versus the tablet.

99P-4167

PAV 1

You may contact Dr. Lonnie W. Luther, Chief, Generic Animal Drug and Quality Assurance Staff, (301) 827-0209, for any questions on the specific requirements for the ANADA submission.

Sincerely yours,



Claire M. Lathers, Ph.D., F.C.P.
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine